

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/461,262	01/05/90	BARBERICH	T SPC8905

EXAMINER  
SCHENKMAN, LHAMILTON, BROOK, SMITH & REYNOLDS  
TWO MILITA DRIVE  
LEXINGTON, MA 02173-4799ART UNIT  
1205

DATE MAILED: 12/09/91

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

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This application has been examined.  Responsive to communication filed on 9/26/91  This action is made final.  
A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice re Patent Drawing, PTO-948.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, Form PTO-152
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.

**Part II SUMMARY OF ACTION**

1.  Claims 1-6, 8, 9, 13 and 14 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2.  Claims \_\_\_\_\_ have been cancelled.
3.  Claims \_\_\_\_\_ are allowed.
4.  Claims 1-6, 8, 9, 13 and 14 are rejected.
5.  Claims \_\_\_\_\_ are objected to.
6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.
7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8.  Formal drawings are required in response to this Office action.
9.  The corrected or substitute drawings have been received on \_\_\_\_\_ Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).
11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).
12.  Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14.  Other

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-6, 8, 9, 13 and 14 are rejected under 35 U.S.C.

§ 103 as being unpatentable over Chemical Abstracts for reasons of record. Applicant's arguments and analysis of the In re Adamson decision are not well taken. The fact that Adamson does not relate to treatment of asthma or use of the claimed isomer is not germane since the claimed isomer has the same type of activity as the racemic mixture.

Claims 1-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Brittain et al., Hartley et al., Hawkins et al. and Buckner et al. for reasons of record. Applicant's argument that the prior art teaches that the (-) isomer and the racemic mixture exhibit the same degree of activity is not universally accepted; note that Hawkins et al. article. In any event, since

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it has been established that the racemic mixture and isomeric forms of the compounds have been used or tested as bronchodilators in the treatment of asthma, the use of compositions containing the claimed isomer in the treatment of asthma is clearly rendered obvious, notwithstanding the inconsistency or the prior art on the this point. The references cited herein would present a strong prima facie case of obviousness even assuming, arguendo, they dealt solely with the racemic mixture.

Claims 6, 8, 9, 13 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Brittain et al. Hartley et al. Hawkins et al. and Bruckner et al. in view of Chemical Abstracts for reasons of record. The fact that Chemical Abstracts does not teach the isomers of Albuterol is not germane to this rejection. Drug combinations containing the (-) isomer would clearly be obvious in view of the teaching of drug combinations containing the racemic mixture.

Claims 9, 13 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 and 14 do not have proper antecedent support in claim 9 which appears to be limited to the (-) isomer. Claims 9, 13 and 14 are again rejected as being too broad absent recitation of amounts of ingredients present. The

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skilled artisan would be hard pressed to determine contemplated proportions; note the functional language of claim 6.

Tan et al. is cited to show the state of the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Schenkman whose telephone number is (703) 308-4651.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*leonard schenkman*  
LEONARD SCHENKMAN  
EXAMINER  
ART UNIT 125

Schenkman: ach  
December 05, 1991